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PATENT
Attorney Docket No.: 021621-000120US

TOWNSEND and TOWNSEND and CREW LLP

By: 
Jody A. Roeder

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

KIRK PATRICK SEWARD et al.

Application No.: 10/691,119

Filed: October 21, 2003

For: METHODS AND KITS FOR
VOLUMETRIC DISTRIBUTION OF
PHARMACEUTICAL AGENTS VIA
THE VASCULAR ADVENTITIA AND
MICROCIRCULATION

Customer No.: 20350

Confirmation No. 5345

Examiner: WITCZAK, CATHERINE

Technology Center/Art Unit: 3767

TELEPHONE INTERVIEW SUMMARY

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Applicants thank Examiner Witczak for the courteous and helpful telephone interview on October 29, 2009. James Heslin, attorney of record, and Kirk Seward, the lead inventor, were on the telephone call on behalf of Applicant. The Beyerlein '297 and Leclerc '197 patents were discussed. The Applicants pointed out, as argued in previous amendments, that Beyerlein does not teach a method for confirming that a substance delivery aperture in a needle has reached the adventitial space. Instead, as described in Beyerlein in paragraphs [0003], [0044], and [0056], Beyerlein describes positioning a needle having a known or selected length within a blood vessel and "advancing the needle until . . . [a] . . . conductive gasket 808 contacts the tissue wall 830." Such contact produces a signal which alerts the user that the

needle has been fully penetrated into the blood vessel wall. Beyerlein then assumes that the needle will have reached the adventitial area so long as the needle length is sufficient. Nowhere does Beyerlein ever teach or suggest the need to actually confirm that the needle has reached the adventitial tissue.

As discussed with the Examiner, the thickness of the vascular wall may vary considerably among patients and within individual patients. Thus, even if a needle length is selected which may be sufficiently long in most instances, there will be some instances when the aperture will not have reached the adventitial space even when the needle is fully engaged against the inner lumen surface. While one might imagine choosing a needle length which is sufficient to reach the adventitia in all cases, such a hypothetical length would likely be too long for routine use.

Thus, even though Beyerlein does have a common objective with the present application, i.e. to position a drug delivery needle within the adventitial layer surrounding a blood vessel, Beyerlein teaches an entirely different solution, i.e. using a long needle and assuring that the needle is fully engaged against the blood vessel wall. The present invention, in contrast, uses injection of contrast media through the aperture of the delivery needle and observance of a distinct infusion pattern to assure that the aperture has reached the adventitia in all cases before the therapeutic substance is actually delivered.

While the Leclerc does teach using contrast media to confirm the position of a drug delivery catheter, the catheter does not include needles which are capable of penetrating the vascular wall. Moreover, as Beyerlein positions its drug delivery needle by assuring proper contact between the needle and the blood vessel wall, there would be no reason to utilize contrast injection as taught by Leclerc in the needle positioning protocols of Beyerlein.

For these reasons, and as agreed to by the Examiner, the present claims are patentably distinguishable over the combination of Beyerlein and Leclerc, and Applicants respectfully request that the present application be passed to issue.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at 650-326-2400.

Appl. No. 10/691,119
Amdt. dated November 10, 2009
Telephone Interview Summary of October 29, 2009

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at 650-326-2400.

Respectfully submitted,

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